

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/821,710  
Filed : April 8, 2004  
Page 7 of 13 of July 12, 2007 Amendment

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Remarks

Claims 44 and 77-141 were pending in the subject application. By this Amendment, Applicants have amended the claims as indicated above to overcome all of the rejections set forth in the January 12, 2007 Final Office Action, and cancelled without prejudice withdrawn claims 114-141. Pursuant to the July 20, 2007 Advisory Action, this Amendment cancels withdrawn claims but is otherwise the same as Applicants' July 12, 2007 claim amendment.

Accordingly, claims 44 and 77-113 as amended herein are currently pending and recite the embodiment indicated to be allowable in the January 12, 2007 Final Office Action, i.e. the embodiment of allowable claim 101. This Amendment, therefore, places all of the pending claims in condition for allowance and should be entered under 37 C.F.R. § 1.116 according to 37 C.F.R. § 41.33(a).

July 20, 2007 Advisory Action  
and outstanding restriction between product claims.

The July 20, 2007 Advisory Action alleged that entry of Applicants' July 12, 2007 Amendment would necessitate consideration of issues such as enablement in connection with the withdrawn claims.

Applicants respectfully maintain that the requirement for restriction between claims directed to an isolated nucleic acid, and claims directed to cells comprising the nucleic acid, is improper. Applicants further submit that no additional issues such as enablement would apply to the withdrawn product claims had they been rejoined. Regardless,

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in an effort to advance prosecution but without conceding the correctness of the Examiner's position, Applicants by this Amendment have cancelled the withdrawn claims. Applicants look forward to the allowance of the claims pending upon entry of this Amendment.

#### Priority

On pages 3-4 of the January 12, 2007 Final Office Action, the Examiner alleged that pending claim 44 has an effective filing date of March 19, 1999, and all of the pending claims have an effective filing date no earlier than March 19, 1999.

Applicants respectfully disagree. For example, while the Examiner alleged that the priority applications reveal no support for a first ribonucleotide sequence of greater than 20 consecutive nucleotides, Applicants respectfully submit that support for the phrase may be found, *inter alia*, on page 25, line 21 of PP 2499, filed March 20, 1998. However, in view of Applicants' amendments herein, Applicants submit that the issue is moot.

#### Oath/Declaration

Applicants are pleased to note that on page 4 of the January 12, 2007 Final Office Action the Examiner stated that the oath or declaration is no longer considered to be defective.

#### Rejection under 35 U.S.C. § 112, first paragraph - New matter

On page 4 of the January 12, 2007 Final Office Action, the Examiner rejected claim 103 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

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In response, to advance prosecution but without conceding the correctness of this rejection, Applicants have herein cancelled claim 103 without prejudice to their right to pursue the subject matter of claim 103 in a related application. Accordingly, the rejection of claim 103 under 35 U.S.C. 112, first paragraph, is moot.

Moot Rejections under 35 U.S.C. §§ 102 and 103

On pages 5-6 of the January 12, 2007 Final Office Action, the Examiner rejected claims 44, 77, 80-87, 90, 91, 97, 98, 104-106, 110, 111, 114, 118, 119, 125-127, 129, 130, and 131 under 35 U.S.C. 102(b) as allegedly anticipated by Agrawal et al. (WO 94/01550, of record).

On page 7, the Examiner rejected claim 102 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al.

On pages 7-8, the Examiner rejected claims 44, 78, 79, 88, 89 and 112 and 113 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al. in view of Day et al. (Proc. Nat Acad. Sci. USA 88:6721-6725, 1991).

On pages 8-10, the Examiner rejected claims 44, 88, 89, 99, 100, 112 and 113 under 35 U.S.C. § 103 as allegedly unpatentable over Agrawal et al. in view of Shewmaker et al. (US patent 5,107,065).

On page 10, the Examiner rejected claims 44, 90, 92 and 94 under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal

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et al. in view of McGarry et al. (Proc. Nat. Acad. Sci. USA  
83:399-403, 1986).

On page 11, the Examiner rejected claims 44, 90 and 92 under  
35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al.  
in view of Powell-Coffman et al (Dev. Biol. 178:472-483,  
1996).

On page 12, the Examiner rejected claims 44, 90, 93 and 95  
under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal  
et al. in view of Barabino et al (Mech.Dev. 63:133-143, 1997).

On pages 12-13, the Examiner rejected claims 44, 90 and 96  
under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal  
et al. in view of Swamynathan et al. (J. Virol. 71(4): 2873-  
2880, 1997).

On pages 13-14, the Examiner rejected claims 44 and 107 under  
35 U.S.C. 103(a) as allegedly unpatentable over Agrawal et al.  
in view of Schreiber et al (US Patent 5,858,981).

On pages 14-15, the Examiner rejected claims 44, 108 and 109  
under 35 U.S.C. 103(a) as allegedly unpatentable over Agrawal  
et al. in view of Dhalla et al (Bichem. J. 336(2): 373-379,  
1998).

*Applicants' response*

In response, to advance prosecution but without conceding the  
correctness of any of the foregoing rejections, Applicants  
have amended the claims to recite the embodiment of claim 101

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which was indicated to be allowable on page 15 of the January 15, 2007 Final Office Action.

Accordingly, Applicants respectfully submit that each of the foregoing rejections is moot.

**The February 23, 2007 and March 6, 2007 "Third Party Submission Under C.F.R. 1.99 In Published Application"**

Applicants note that a third party has filed two submissions under 37 C.F.R. § 1.99. These submissions are defective and should not have been made of record.<sup>1</sup>

Regardless, for the convenience of the Examiner, Applicants are making of record by the concurrently filed Information Disclosure Statement an April 24, 2007 Amendment filed in Reexamination Control No. 90/007,247, which is a reexamination of related U.S. Patent No. 6,573,099. The April 24, 2007 Amendment addresses all but one of the references submitted by the third party.

The claims being discussed in the reexamination are different from the claims pending in the subject application. Nonetheless, the element of a "stuffer fragment" is common to certain claims of the patent in reexamination and all of the

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<sup>1</sup> The February 23, 2007 and the March 6, 2007 "Third Party Submission Under C.F.R. 1.99 In Published Application" are each untimely under 37 C.F.R. § 1.99(e) and should both be stricken from the record for being untimely. The subject application published November 25, 2004. Each of the references submitted with the third party submissions have been available since January 14, 2003 or earlier. The third party submissions have been filed more than two (2) years after the publication of the subject application and over four (4) years after the latest patent or publication was

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pending claims of the subject application, and a January 24, 2007 Office Action in the re-examination on page 19 acknowledged that "The Fire et al. patent [U.S. 6,506,559] and the PGPUB 10/282,996 application differ [from the '099 patent] by not specifically teaching a nucleic acid stuffer fragment as recited in claims 5 and 9 of the instant '099 patent." Applicants also point out that the April 24, 2007 Amendment in the reexamination includes a Declaration under 37 C.F.R. §1.131 to remove as a reference several of the documents submitted by the third party. Furthermore, the claims of the subject application as amended herein recite additional features (e.g., an intron) which are neither taught nor suggested by the submitted references.

Accordingly, besides being an improper submission, the submission is of references which do not anticipate or make obvious the invention now claimed in the subject application.

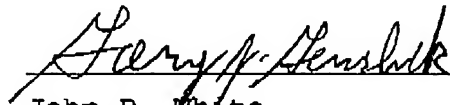
#### *Conclusion*

Applicants respectfully request that the Examiner advance the subject application to allowance. If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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